## REMARKS

### Status of the Claims

Claims 1, 2, 10-13, 16-22 and 41-81 are in the application.

Claims 16-22, 48-54, 61-67 and 75-81 have been withdrawn from consideration.

Claims 1, 2, 10-13, 41-47, 55-60 and 68-74 have been rejected.

By way of this amendment, claims 1, 2, 10-13, 41-47, 55-60, 68-70 and 72-74 have been amended and new claims 82-88 have been added.

Upon entry of this amendment, claims 1, 2, 10-13, 16-22 and 41-88 will be pending, of which claims 1, 2, 10-13, 41-47, 55-60, 68-74 and 82-88 will be considered for examination at this time.

### Summary of the Amendment

Claims 1, 2, 42, 55, 68 and 69 has been amended to expressly refer to the CD80 mutant protein as a human CD80 mutant protein and its components regions as being from human CD80. Support is found throughout the specification including pages 5 and 6.

Claim 1 has been amended to delete the term "functional 80C."

Claims 1 and 43 have been amended to correct obvious errors: the word "that" has been deleted from claim 1; the word "acid" has been added to claim 43.

Claim 1 has been amended to refer to change the word "transmute" to "provide" and refer to the functional property of the mutant CD80 protein as "possesses costimulatory activity of wild-type CD80." Support is found throughout the specification including page 5.

Claims 2, 10-13, 41-47, 55-60, 68-70 and 72-74 have been amended to use the dependency phrase "according to" in place of the term "of" when referring to the claim from which the subject claim depends.

Claim 55 has been amended to refer to change the word "transmute" to "provide"

New claim 83-88 correspond to claims 42-47, respectively, but new claims 82 is dependent on claim 2.

No new matter has been added.

**Oath**

The previously filed declaration has been deemed defective as having non-initialed/non-dated alterations. A new declaration is provided herewith.

**Objections**

Claim 1 has been objected to as containing a superfluous inclusion of the word "that." Claim 1 has been amended to correct this error.

Claim 43 has been objected to as omitting the word "acid." Claim 43 has been amended to correct this error.

Applicants respectfully request that the objections to claims 1 and 43 be withdrawn.

**Rejection under 35 U.S.C. §112, second paragraph**

Claims 1-2, 10-13, 41-47, 55-60 and 68-74 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicants regard as the invention.

It is asserted that the terms "functional 80C" and "function fragment" renders the claims indefinite.

Claim 1 has been amended to delete the term "functional 80C."

The term functional fragment is clear and definite in view of the specification. moreover, claims 2 and 42-47 do not refer to functional fragments and claims 68-74 refer to specific fragments.

It is asserted that the term "80C" renders the claims indefinite.

Claim 1 has been amended to delete the term "80C."

It is asserted that the reference to "said CD80" in the last part of claim 1 renders the claims indefinite.

Claim 1 has been amended to refer to "said mutant CD80 protein."

It is asserted that the term "transmute" renders the claims indefinite.

Claim 1 has been amended to replace "transmute" with the term "provide" (see page 5, line 11 of the specification).

Applicants respectfully request that the rejection of claims 1, 2, 10-13, 41-47, 55-60 and 68-74 under 35 U.S.C. §112, second paragraph, be withdrawn.

**Rejection under 35 U.S.C. §112, first paragraph**

Claims 1, 10-13, 41-47, 55-60 and 68-74 have been rejected under 35 U.S.C. §112, first paragraph, because it is asserted that the specification is not enabling for functional fragments.

Applicants respectfully disagree. Metzler, which is cited as indicating that numerous amino acids are critical for CTLA4 activity, does not support the position that those skilled in the art would question the objective truth of applicants' assertion that the invention is enabled. The fact that a given protein has amino acids essential for its activity is completely consistent with the idea of functional fragments. Metzler does not teach that all amino acids are required. Rather, the teaching does not support a conclusion that the specification does not enable the claims. Those skilled in the art would accept applicants assertion that fragment of the protein regions could be used in place of their full length equivalents. One skilled in the art would be surprised if this wasn't the case.

Claims 10-13 and 41 have been rejected under 35 U.S.C. §112, first paragraph, because it is asserted that the claims refer to fragments of the nucleic acids specified in claim 1. Claims 10-13 and 41 have been amended to eliminate the basis for the rejection.

Claims 13, 47, 60 and 74 have been rejected under 35 U.S.C. §112, first paragraph, because it is asserted that the one skilled in the art would not conclude that claims to vaccines were enabled.

Applicants respectfully disagree. Singh, which is cited as showing that adjuvants used *in vitro* have been found to be too toxic when tested *in vivo*, does not support the position that those skilled in the art would question the objective truth of applicants' assertion that the invention is enabled. The fact that other adjuvants have been found to be toxic does not support an assertion that one skilled in the art would expect such results. Singh does not teach that *in vitro* results are without value. Rather, the teaching does not support a conclusion that the specification does not enable the claims. Those skilled in the art would accept applicants assertion that the claimed human CD80 mutant protein would be useful as a vaccine adjuvant based upon the data and applicants assertions.

Applicants respectfully request that the rejection of claims 1, 10-13, 41-47, 55-60 and 68-74 under 35 U.S.C. §112, first paragraph, be withdrawn.

**Rejection under 35 U.S.C. §102**

Claims 1, 2, 10-13 and 41-47 have been rejected under 35 U.S.C. §102(b) as being anticipated by Linsley et al U.S. Patent 5,580,756 (the 756 Patent).

It is asserted that the amino acid sequences referred to in the specification disclose a CD80 mutant with a truncated C region. Applicants respectfully urge that construct would, contrary to the requirements of the claimed invention, provide the negative the signal associated with wild-type human CD80 C region interactions with human CTLA4. The 756 Patent construct is simply a truncated form of the protein and includes the essential regions of CD80 C region, as set forth in Table 6.

The 756 Patent does not anticipate the claimed invention. Applicants respectfully request that the rejection of claims 1, 2, 10-13 and 41-47 under 35 U.S.C. §102(b) as being anticipated by Linsley et al U.S. Patent 5,580,756 (the 756 Patent) be withdrawn.

Claims 1, 2, 10-13, 41-47, 55-60 and 68-74 have been rejected under 35 U.S.C. §102(e) as being anticipated by Sharpe et al U.S. Patent 6,294,660 (the 660 Patent).

It is asserted that the amino acid sequences referred to in the specification disclose a CD80 mutant with a deleted C region. Applicants respectfully point out that the construct set forth in the 660 Patent is a murine construct, not a human construct. Moreover, claims 2 and 42- 47 require residues of the C region to be present.

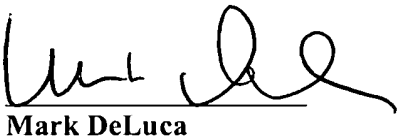
The 660 Patent does not anticipate the claimed invention. Applicants respectfully request that the rejection of claims 1, 2, 10-13, 41-47, 55-60 and 68-74 under 35 U.S.C. §102(e) as being anticipated by Sharpe et al U.S. Patent 6,294,660 (the 660 Patent) be withdrawn.

**Conclusion**

Claims 1, 2, 10-13, 41-47, 55-60, 68-74 and 82-88 are in condition for allowance. An indication of allowability and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

Dated: Oct 16 2004



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